



Guidelines for Certification
of a
Physical Containment Level 2
Aquatic Organism Facility
Version 2.1– issued 1 September 2006

These guidelines contain the requirements for certification of a Physical Containment Level 2 (PC2) Aquatic Organism Facility pursuant to section 90 of the *Gene Technology Act 2000* (the Act).

The Conditions of Certification detail the usual conditions that will apply to a PC2 Aquatic Organism Facility pursuant to section 86 of the Act and are attached to this document.

The standards that are referenced in the requirements and conditions are also attached to this document.

A separate document - *Explanatory Information on Guidelines for Certification of Physical Containment Facilities* - contains details about the process of certification.

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Requirements for Certification

Physical Containment Level 2 Aquatic Organism Facility Version 2.1 – issued 1 September 2006

CONTAINMENT REQUIREMENTS THAT MUST BE MET IN ORDER FOR A PHYSICAL CONTAINMENT LEVEL 2 (PC2) AQUATIC ORGANISM FACILITY TO BE CERTIFIED BY THE GENE TECHNOLOGY REGULATOR (THE REGULATOR).

Section 90 of the *Gene Technology Act 2000*

These are the requirements for the certification of a PC2 Aquatic Organism Facility issued under section 90 of the Act and corresponding State legislation. These requirements apply to applications for certification of PC2 Aquatic Organism Facilities received on or after the day on which these guidelines take effect.

Definitions

Unless defined otherwise in these guidelines words and phrases used in the guidelines have the same meaning as the Act and the *Gene Technology Regulations 2001* (the Regulations).

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

aerosol Particulate matter, solid or liquid, small enough to remain suspended in air.

airlock An area or room between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**.

The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.

The **airlock** can function as a clothes change room (showers may be included), but must not be used for performing any **procedures** on organisms.

The term **airlock** is used only in relation to PC3 and PC4 facilities.

anteroom	<p>An area or room between a pair of doors through which access is had to the work area inside a facility.</p> <p>The anteroom does not have to perform the same airflow control function as an airlock, but an airlock can perform the role of anteroom.</p> <p>The anteroom must not be used for performing any procedures on organisms.</p> <p>The term anteroom is used only in relation to PC1 and PC2 facilities.</p>
autoclave	Pressure steam steriliser.
bunding	Provision of a low wall around potential spillage areas.
competent person	A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to perform a specified task.
dealings or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none"> (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; <p>and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).</p>
decontamination	A physical or chemical process which kills or renders non-viable the organisms used in the facility , but does not necessarily result in sterility.
environment	<p>Includes:</p> <ul style="list-style-type: none"> (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified facility comprises the work area and any anteroom or airlock used to enter or leave the facility's work area .

procedures	The meaning of procedures includes any activity involving work with organisms inside a facility .
work area	Any area inside a facility that is not performing the function of an airlock or anteroom . Procedures on GMOs may take place in the work area and any procedures in the work area are subject to the conditions on the certification instrument.

General

1. To be granted certification a **facility** must meet each of the containment requirements for certification of a PC2 Aquatic Organism Facility unless the **facility** receives an exemption from meeting a particular requirement from the Regulator or a delegate of the Regulator.

Facility requirements

2. If the **facility** is located in an area that is prone to flooding or storm surges, approval of the application for certification will depend on an assessment of the risks of GMOs escaping in a flood or storm surge event. The application must include details of the GMOs that will be kept in the **facility**; details about the magnitude and likelihood of flooding or storm surges; and details of **facility** design features and risk management **procedures** that will ensure no GMOs escape from the **facility** during a flood or storm surge event.

NOTE: Persons planning an aquatic **facility** in an area that is prone to flooding or storm surges and who intend to apply for certification by the Regulator are encouraged to contact the Office of the Gene Technology Regulator (OGTR) prior to or during the planning phase.

Risk management **procedures** might include, for example, removal or destruction of GMOs, and **decontamination** of all water in the primary containers, secondary containers and effluent treatment system, well before inundation occurs. The scale of the **dealings** conducted in the **facility** must be small enough to allow time for these **procedures** to be completed.

For the purposes of these guidelines, flooding includes:

- mainstream flooding (an event where water from a creek, river, lake, estuary or coastal waters overflows the natural or artificial banks of the principal watercourses in a catchment);
- flash flooding (flooding that occurs within six hours of the rain which causes the flooding); and
- stormwater flooding (local runoff exceeding the capacity of an urban stormwater drainage system).

For the purposes of these guidelines, a storm surge is a rise in coastal water levels caused by the low pressure area of a storm or cyclone and wind driving water shorewards.

For the purposes of these guidelines, the determination of whether the location of the **facility** is prone to flooding or storm surges depends on the expected frequency of these events. The **facility** will be regarded as being prone to flooding if the floor of the **facility** would be inundated by a 100 year Average Recurrence Interval (ARI) flood or storm surge event. (This equates to a 1 in 100 year flood level, or an Annual Exceedence Probability (AEP) of 1%). If it is not possible to obtain the 100 year ARI flood level from the relevant local authority, then the highest ARI or Defined Flood level used by that authority will be taken to be the level for determining if the location is prone to flooding or storm surges.

For **facilities** prone to flooding or storm surges, details about the flooding should include the likely effective warning time that the **facility** would have prior to inundation and possible hazards that might prevent the implementation of any risk management **procedures** (such as staff being unable to reach the **facility** prior to inundation). Applicants should expect the Regulator to seek further details during the assessment of the application.

3. The **facility** must be a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be lockable. The **facility** must be designed to prevent the entry of surface run-off water or the surface run-off must be diverted around the **facility**.
4. The floors of the **facility**, including any **bundling**, must be made of a durable material that is impervious to water and any joins between the floor and the **bundling** must be sealed.
5. The **facility** must have a system for the **decontamination** of liquid effluent that contains, or is suspected of containing, aquatic GMOs or genetically modified (GM) pathogens. This effluent includes that from the wash-up of equipment such as primary and secondary containers, filters, nets, and any other equipment that does or may contain aquatic GMOs or GM pathogens.
6. If the **facility** has floor drainage exits, all effluent from these drains must be filtered, or **decontaminated** by heat or chemical treatment, before being discharged.

NOTE: The **facility** may be designed so that the effluent from drainage exits and other liquid effluent from the **facility** is filtered through or **decontaminated** by the same system.

Discharge into municipal sewers of effluent that has not been filtered or **decontaminated** is not an adequate barrier to the unintended escape of aquatic GMOs in most cases because sewers may bypass to storm water systems during high-runoff events, and must not occur in any

circumstance for species that might survive passage through the sewer and treatment plants.

7. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
8. If the work in the **facility** will involve GM pathogens, or there will be hand contact with GMOs that could persist on the hands after exit from the **facility**, the **facility** must contain either a wash basin fitted with tap(s) of the hands-free operation type or some other means of **decontaminating** hands.

NOTE: Alternatives to wash basins, such as dispensers filled with disinfectant solutions, are considered suitable, provided the dispensers can be operated without using the hands.

9. Where any device or system will be connected directly or indirectly to the water supplied to the **facility** that may allow GMOs to escape into **environment** via the water supply to the **facility** water service, then backflow prevention measures must be implemented in accordance with the requirements of Section 4 of AS/NZS 3500.1:2003.

NOTE: Section 4 of AS/NZS 3500.1:2003 specifies the requirements and methods for the prevention of backflow into water services and water mains and provides for the selection and installation of backflow prevention devices.

The water supply to an aquatic **facility** may come from more than one source. There may be, for example, a dedicated supply for the aquarium systems and a municipal, potable, supply for wash-up and use by **facility** staff.

Cross-connection might occur with the municipal system in cases such as a hose being used for cleaning out secondary containment (e.g. floor **bundling**) or a floor-drain sump falling into effluent water.

If the water supply is a dedicated supply, such as a storage tank dedicated for use inside the **facility**, then back-siphonage is unlikely and would not need a backflow prevention device. However, if back-pressure from any pumps attached to the water supply might force water back into the tank and the pressure is sufficient to cause overflow from the tank, backflow protection would be necessary.

10. If the work in the **facility** will involve GM pathogens, or there will be contact with any GMOs that could persist on clothing after exit from the **facility**, then designated storage or hanging provisions for protective clothing must be available in the **facility**.

Containment equipment requirements

11. The **facility** must be fitted with sufficient primary containers (eg tanks) to contain the aquatic organisms to be kept in the **facility**. If there is any likelihood of the formation of **aerosols** containing GM pathogens or viable GMOs (such as the larvae of bivalves and some crustaceans, or viable aquatic plant material) then the **aerosols** must be prevented from escaping the **facility** by covering the primary containers or filtering any exhaust air.
12. Secondary containment must be provided to retain and **decontaminate** any spillage of water from:
 - breakage of, leakage from, or overflow from, primary container(s); or
 - overflow or leakage from aquarium water circulation systems that could contain GMOs.

The total volume to be retained must be calculated to include:

- the volume of a percentage of the primary containers;
- an estimate of the total volume of any potential overflow or leakage from aquarium water circulation systems that could contain GMOs;
- the volume of any disinfectant that might be used; and
- additional capacity to prevent any expected general fluid movement from splashing over the top of the secondary containment.

The percentage of the primary container volume is determined as follows:

- where the number of primary containers is ten or less, the volume of the largest container;
- where the number of primary containers is greater than ten, the total volume of 10% of the containers using the volume of the largest containers (e.g. for 28 containers, the largest 3 containers).

NOTE: In **facilities** where the total volume of water to be retained is sufficiently small relative to the floor area of the **facility** such that water cannot flow out of the **facility**, there may be no need for secondary containment.

The secondary containment could consist of **bunding** or some other containment such as holding trays under individual tanks or racks of tanks. If the **facility** has an effluent **decontamination** system for retaining drainage from the **facility** floors, and the system is large enough to retain and treat any overflow or leakage that drains onto the floor, then the effluent **decontamination** system may be used as the secondary containment.

Capacity to comply with certification conditions

13. The **facility** must be able to demonstrate that it is capable of complying with the conditions of certification that will be applied to a certified PC2 Aquatic Organism Facility, as attached to these requirements.

Conditions of Certification

Physical Containment Level 2 Aquatic Organism Facility Version 2.1 – issued 1 September 2006

Conditions are imposed on **facilities** by the Regulator at the time of certification pursuant to section 86 of the Act. The condition clauses in this section are the ones that can be expected, in most cases, to be included on the certification instrument as the conditions of certification for a Physical Containment Level 2 (PC2) Aquatic Organism Facility.

Definitions

Unless defined otherwise in these conditions words and phrases used in the conditions have the same meaning as the Act and the *Gene Technology Regulations 2001* (the Regulations).

Words in the singular include the plural and words in the plural include the singular.

Where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning.

- aerosol** Particulate matter, solid or liquid, small enough to remain suspended in air.
- airlock** An area or room between a pair of doors that separates the **work area** inside a **facility** from access corridors, other laboratories, or other spaces outside the **facility**.
- The **airlock** permits the movement of equipment and personnel without affecting the inward flow of air into the **work area**, since at least one door is kept closed at all times.
- The **airlock** can function as a clothes change room (showers may be included), but must not be used for performing any **procedures** on organisms.
- The term **airlock** is used only in relation to PC3 and PC4 facilities.

anteroom	<p>An area or room between a pair of doors through which access is had to the work area inside a facility.</p> <p>The anteroom does not have to perform the same airflow control function as an airlock, but an airlock can perform the role of anteroom.</p> <p>The anteroom must not be used for performing any procedures on organisms.</p> <p>The term anteroom is used only in relation to PC1 and PC2 facilities.</p>
autoclave	Pressure steam steriliser.
bunding	Provision of a low wall around potential spillage areas.
competent person	A person who has acquired through training, qualifications or experience, or a combination of these, the knowledge and skill enabling that person to perform a specified task.
dealings or deal with	<p>In relation to a GMO, means the following:</p> <ul style="list-style-type: none"> (a) conduct experiments with the GMO; (b) make, develop, produce or manufacture the GMO; (c) breed the GMO; (d) propagate the GMO; (e) use the GMO in the course of manufacture of a thing that is not the GMO; (f) grow, raise or culture the GMO; (g) import the GMO; <p>and includes the possession, supply, use, transport or disposal of the GMO for the purposes of, or in the course of, a dealing mentioned in any of the paragraphs (a) to (g).</p>
decontamination	A physical or chemical process which kills or renders non-viable the organisms used in the facility , but does not necessarily result in sterility.
environment	<p>Includes:</p> <ul style="list-style-type: none"> (a) ecosystems and their constituent parts; (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas.
facility	The whole of the space that is to be certified by the Regulator to a specific level of containment. A certified facility comprises the work area and any anteroom or airlock used to enter or leave the facility's work area .

procedures The meaning of **procedures** includes any activity involving work with organisms inside a **facility**.

work area Any area inside a facility that is not performing the function of an **airlock** or **anteroom**.

Procedures on GMOs may take place in the **work area** and any **procedures** in the **work area** are subject to the conditions on the **certification** instrument.

Work not permitted in this facility type

1. The following work must not be conducted in this **facility**:
 - (a) work with any GMO that under the Act, or under the conditions of a licence, requires containment in any physical containment level higher than PC2;
 - (b) work with non-aquatic GMOs unless they have been inoculated into the aquatic organisms being contained in the **facility**;
 - (c) the housing/keeping/rearing of terrestrial animals or terrestrial arthropods;
or
 - (d) the growing of any terrestrial plants.

Compliance with certification conditions

2. All the conditions listed under the heading of ‘Facility Conditions’, ‘Containment Equipment’ and ‘Facility Management’ must be complied with at all times whether or not the **facility** is being used for a **dealing** with a GMO. The certification holder must notify the Regulator in writing when the **facility** is no longer able to meet these conditions. This notification may include an application for a variation to the conditions and must also include an alternative, effective strategy to manage any risks associated with **dealings** with GMOs in the **facility**.

The conditions listed under ‘Personal Protective Clothing and Equipment’ and ‘Work Practices’ must be complied with at all times if a **dealing** with a GMO is being conducted in a **facility**. This condition applies whether or not work with a non-GMO is occurring in the **facility** at the same time.

NOTE: A GMO dealing includes possession, supply, use, transport and disposal of a GMO for the purposes of a **dealing**. Storage of a GMO, for example, constitutes a **dealing** with a GMO.

Facility conditions

3. The **facility** must be labelled with the following adhesive signs:
 - (a) a PC2 sign, as supplied by the OGTR; and
 - (b) a biohazard symbol.

The signs must be placed on or next to each access door to the **facility** so that persons entering the **facility** are able to clearly see they are entering a certified PC2 **facility**.

NOTE: Signs do not need to be displayed on or next to the outside of emergency exits (which are not to be used to enter the **facility**). Signs may be stuck onto removable fixtures, such as backing boards or plastic frames, which must be secured to the door or wall and must not be transferred to any other location.

4. The **facility** must be maintained as a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be maintained so they are lockable. The **facility** or the area around the facility must be maintained so that the entry of surface run-off water is prevented.

Any changes to the physical structure of a **facility** must not affect compliance with these conditions of certification. Prior to any structural changes that will affect the containment of GMOs, the applicant must cease all **dealings** with GMOs and request a suspension of the certification, in writing, from the Regulator.

In order to lift the suspension, the **facility** must be inspected after the structural changes are completed to ensure that the **facility** meets the requirements for certification. **Dealings** with GMOs may not commence until the Regulator has lifted the suspension by approval in writing.

NOTE: The certification holder can arrange for any **competent person** to inspect the **facility** to assess compliance with these conditions of certification. Proforma inspection checklists are available on the OGTR web site <www.ogtr.gov.au> but their use is not mandatory. A record of the result of the inspection may be requested by the Regulator to support requests to lift the suspension of the certification, but in all cases the outcome of the inspection must be notified before the suspension can be lifted.

5. The floors of the **facility**, including any **bundling**, must be maintained as durable and impervious to water, and any joins between the floor and the **bundling** must remain sealed.
6. The **facility** must have a system for the **decontamination** of liquid effluent containing, or suspected of containing GMOs or pathogens used in conjunction with GMOs. This effluent includes that from the wash-up of equipment such as primary and secondary containers, filters, nets, and any other equipment that does or may contain aquatic GMOs or GM pathogens.
7. If the **facility** has floor drainage exits, all effluent from these drains must be **decontaminated** before being discharged.

NOTE: The floor drainage effluent **decontamination** treatment system may be the same system that handles other liquid effluent from the **facility**.

Discharge into municipal sewers of effluent that has not been **decontaminated** is not an adequate barrier to the unintended escape of aquatic GMOs in most cases because sewers may bypass to storm water systems during high-runoff events, and must not occur in any circumstance for species that might survive passage through the sewer and treatment plants.

8. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning.
9. If the work in the **facility** involves GM pathogens, or there is hand contact with GMOs that could persist on the hands after exit from the **facility**, the **facility** must contain either a wash basin fitted with tap(s) of the hands-free operation type or some other means of **decontaminating** hands.

NOTE: Alternatives to wash basins, such as dispensers filled with disinfectant solutions, are considered suitable, provided the dispensers can be operated without using the hands.

10. Where any device or system will be connected directly or indirectly to the water supplied to the **facility** that may allow GMOs to escape into **environment** via the water supply to the **facility** water service, then backflow prevention measures must be implemented in accordance with the requirements of Section 4 of AS/NZS 3500.1:2003.

NOTE: Section 4 of AS/NZS 3500.1:2003 specifies the requirements and methods for the prevention of backflow into water services and water mains and provides for the selection and installation of backflow prevention devices.

The water supply to an aquatic **facility** may come from more than one source. There may be, for example, a dedicated supply for the aquarium systems and a municipal, potable, supply for wash-up and use by **facility** staff.

Cross-connection might occur with the municipal system in cases such as a hose being used for cleaning out secondary containment (e.g. floor **bundling**) or a floor-drain sump falling into effluent water.

If the water supply is a dedicated supply, such as a storage tank dedicated for use inside the **facility**, then back-siphonage is unlikely and would not need a backflow prevention device. However, if back-pressure from any pumps attached to the water supply might force water back into the tank and the pressure is sufficient to cause overflow from the tank, backflow protection would be necessary.

11. If the **facility** is fitted with any testable water supply backflow prevention devices (in accordance with AS/NZS 3500.1:2003), these devices must pass a test every 12 months. These tests must be conducted in accordance with AS 2845.3:1993 by a licensed plumber accredited to test backflow prevention devices. Documentation of the last 5 year's test results must be made available to the Regulator, if requested.
12. If the work in the **facility** involves GM pathogens, or there is contact with GMOs that could persist on clothing after exit from the **facility**, then designated storage or hanging provisions for protective clothing must be available in the **facility**.
13. If the work in the **facility** involves GM pathogens, or GMOs that could persist on **facility** surfaces a supply of disinfectants effective against these GMOs must be available in the **facility** for **decontamination** purposes. Containers of disinfectants must be clearly labelled with the contents and, where necessary, the expiry date.
14. Aquatic organisms in the **facility** must be contained in primary containers. If there is any likelihood of the formation of **aerosols** containing GM pathogens or viable GMOs (such as the larvae of bivalves and some crustaceans, or viable aquatic plant material) then the **aerosols** must be prevented from escaping the **facility** by covering the primary containers or filtering any exhaust air.

Containment equipment conditions

15. Secondary containment must be provided to retain and **decontaminate** any spillage of water from:
 - breakage of, leakage from, or overflow from, primary container; or
 - overflow or leakage from aquarium water circulation systems that could contain GMOs.

The total volume to be retained must be calculated to include:

- the volume of a percentage of the primary containers;
- an estimate of the total volume of any potential overflow or leakage from aquarium water circulation systems that could contain GMOs;
- the volume of any disinfectant that might be used; and
- additional capacity to prevent any expected general fluid movement from splashing over the top of the secondary containment.

The percentage of the primary container volume is determined as follows:

- where the number of primary containers is ten or less, the volume of the largest container;

- where the number of primary containers is greater than ten, the total volume of 10% of the containers using the volume of the largest containers (e.g. for 28 containers, the largest 3 containers).

NOTE: In **facilities** where the total volume of water to be retained is sufficiently small relative to the floor area of the **facility** such that water cannot flow out of the **facility**, there may be no need for secondary containment.

The secondary containment could consist of **bunding** or some other containment such as holding trays under individual tanks or racks of tanks. If the **facility** has an effluent **decontamination** system for retaining drainage from the **facility** floors, and the system is large enough to retain and treat any overflow or leakage that drains onto the floor, then the effluent **decontamination** system may be used as the secondary containment.

Facility management

16. Access to the **facility** must be restricted to authorised persons.

NOTE: Access can be restricted by means such as: keys, key cards or combination locks for entry to the **facility**; or controlled access to the building where the certified **facility** is only a part of a larger building.

17. All **facility** personnel must be trained in the use of equipment present in the **facility** and also in the **procedures** to be used in the **facility**. Records of this training must be kept and made available to the Regulator if requested.

NOTE: The required training should include transport, disposal, identification of hazards associated with the GMO and emergency procedures, certification requirements and licence conditions.

18. The **facility** must be inspected at least once every 12 months. The inspection report must detail the extent of compliance with the conditions of certification and a copy of the last 5 year's inspection reports must be provided to the Regulator if requested.

NOTE: The certification holder can arrange for any **competent person** to inspect the **facility** to assess compliance with these conditions of certification. Proforma inspection checklists are available on the OGTR web site <www.ogtr.gov.au> but their use is not mandatory for annual inspections. Inspection reports should not be sent to the Regulator unless requested.

Personal protective clothing and equipment

19. The following personal protective clothing must be worn by personnel performing **procedures** in the **facility**:
 - (a) laboratory coat or gown, or equivalent, to protect the arms and front part of the body from spills or any other source of contamination (when performing **procedures** that involve GM pathogens or there is contact with GMOs that could persist on the clothing after exit from the **facility**); and
 - (b) gloves (when performing **procedures** that might lead to contamination of the hands, if working with GM pathogens that are hazardous to humans).
20. If the work in the **facility** involves GM pathogens, or there is contact with GMOs that could persist on the clothing after exit from the **facility**, then laboratory coats, gowns or equivalent, must be removed before leaving the **facility** and stored in designated storage or hanging provisions. This condition does not apply if moving directly to another containment **facility**, certified to PC2 by the Regulator, that is directly connected to the **facility**.

Work practices

21. **Facility** doors must remain closed while work is being undertaken in the **facility** and must be locked when the **facility** is unattended.
22. The **facility** windows must be closed and locked while GMOs are in the **facility**.
23. Work benches, surfaces and equipment must be **decontaminated** after completion of **procedures** involving GM pathogens or GMOs that could persist on **facility** surfaces.
24. All work surfaces and equipment where maintenance is to be carried out must be **decontaminated** prior to maintenance taking place if **procedures** involving GM pathogens or GMOs that could persist on **facility** surfaces have been conducted there.
25. **Decontamination** of GMOs or items or material contaminated with GMOs must be performed as follows:
 - GMOs and aquatic organisms containing GMOs must be rendered non-viable prior to disposal.
 - All liquid effluent that contains, or is suspected of containing, aquatic GMOs or GM pathogens, must be **decontaminated** before discharge to prevent the escape of viable GMOs. The **decontamination** method must be effective against the GMOs that may be contained in the effluent.
 - Solid wastes containing GMOs must be **decontaminated** prior to disposal.
 - Equipment must be **decontaminated** prior to use in another location.
 - Protective clothing contaminated with GM pathogens or with GMOs that can persist on the clothing must be taken off as soon as practicable and

decontaminated prior to reuse. Protective clothing that has not been contaminated with GM pathogens may be washed using normal laundry methods.

Except for liquid effluent, **decontamination** can take place in the **work area** of the **facility**, or at another location providing the organisms or waste are transported to the **decontamination** site in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.

NOTE: Effluent includes that from the wash-up of equipment such as primary and secondary containers, filters, nets, and any other equipment.

26. **Decontamination** can be effected by: pressure steam sterilisation (**autoclaving**) or other heat treatment; chemical treatment; incineration; or by any other method approved in writing by the Regulator.

Any heat treatment must be performed using a combination of temperature and time that has been validated as effective against the organisms being rendered non-viable.

Chemical disinfectant treatment must be effective against the organisms being rendered non-viable.

Incineration must be performed in a high temperature, high efficiency incineration facility that has been approved by the relevant government authority in the jurisdiction where the incinerator is located.

27. Where use of a pressure steam steriliser (**autoclave**) is required for sterilisation purposes:

- (a) Loads must be packed and loaded to allow for the penetration of steam into the material being sterilised in accordance with Clauses 6.6.3 or 6.6.4 of AS/NZS 2243.3:2002.
- (b) The coldest part of the load must be exposed to a minimum temperature of 121° C for at least 15 minutes in accordance with Clause 6.6.5 of AS/NZS 2243.3:2002.
- (c) Measures must be taken to ensure that loads that have been processed can be differentiated from loads that have not (e.g. by use of **autoclave** tape).

The efficacy of the sterilisation treatment must be validated at least monthly by the use of:

- (d) thermocouples or resistance thermometers, to ensure that the sterilisation temperature has been achieved; or
- (e) chemical indicators which progressively change colour with the time exposed at the specified temperature; or
- (f) biological indicators such as spore strips; or
- (g) enzyme indicators.

Calibration of the **autoclave** thermometer and timers, and pressure testing of the vessel, must be performed annually by a **competent person**. The results of the autoclave tests, including evidence of the calibration of the equipment used, must be kept for the previous 5 years and made available to the Regulator, if requested.

If an **autoclave** is found to be defective and the defect has not been corrected, the **autoclave** must be clearly marked to show that it is defective and must not be used for **decontaminating** organisms, waste or equipment associated with **dealings** with GMOs until the defect has been corrected.

28. Organisms that are not GMOs must not be removed from the **facility** while a **dealing** with a GMO is occurring in a **facility** unless:
- (a) **procedures** are implemented to ensure that **dealings** with GMOs do not mix with or contaminate work with any other organisms that are not part of the **dealing**;
 - (b) the above **procedures** are documented; and
 - (c) all primary containers and transport containers are **decontaminated** prior to removal from the **facility**.

If mixing or cross-contamination of any other work by GMOs occurs, or is suspected to have occurred, then the other work must be handled and disposed of in accordance with the conditions of certification, as if it were **dealing** with a GMO.

NOTE: Means of preventing cross-contamination of other work by GMO **dealings** could include physical separation of the work, or separation by working at different times and ensuring any contaminated surfaces are **decontaminated** prior to commencing different work.

29. Viable aquatic GMOs must not be removed from the **facility** unless:
- (a) they are to be transported to an aquatic containment **facility** certified by the Regulator to at least PC2;
 - (b) they are to be transported to another location for storage;
 - (c) rendered non-viable prior to disposal; or
 - (d) written permission has been given by the Regulator for transport to another destination.
30. All GMOs, and material contaminated with GMOs, being transported out of the **facility** must be transported in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.
31. GMOs or organisms infected with GMOs being stored outside the certified **facility** must be double-contained. The primary container must be sealed and leak proof. The primary container must be clearly labelled so it can be identified and must be stored in an unbreakable secondary container. In the case of a small storage unit such as a fridge, freezer or liquid nitrogen container, the secondary container may be the storage unit.

NOTE: 'Breakable' here means the container will not break open and its contents leak out if dropped on the floor.

32. Transport of GMOs between the certified **facility** and the storage unit must be in accordance with any transport guidelines and other relevant guidelines, as in force from time to time, issued by the Regulator.

Any spills of GMOs that occur outside the certified **facility** must be reported to the Regulator as soon as practicable. The spilt material and any contaminated surfaces must be **decontaminated**.

33. All primary containers must be labelled to enable identification of the organism being contained.
34. Any unintentional release or suspected unintentional release of GMOs from the **facility** must be reported to the Regulator as soon as practicable.
35. Persons who have been performing **procedures** in the **facility** that involve GM pathogens, or where there has been hand contact with GMOs that could persist on the hands after exit from the **facility**, must **decontaminate** their hands before leaving the **work area**. This can be achieved by washing, or use of appropriate chemical **decontaminant**.

NOTE: Alternatives to wash basins, such as dispensers filled with disinfectant solutions, are considered suitable, provided the dispensers can be operated without using the hands.

Standards referenced in this document

‘AS’ followed by a number or other identification is a reference to the Australian Standard so numbered or identified, as in force or existing from time to time.

‘AS/NZS’ followed by a number or other identification is a reference to the Australian New Zealand Standard so numbered or identified, as in force or existing from time to time.

AS/NZS 2243.3	Safety in laboratories Part 3: Microbiological aspects and containment facilities
AS 2845.3	Water supply - Backflow prevention devices Part 3: Field testing and maintenance
AS/NZS 3500.1	Plumbing and drainage Part 1: Water services